40 CFR Parts 766 and 799

[OPTS-40020; FRL 3840-8]

RIN 2070-AB97

Technical Amendments to Test Rules and Consent Orders

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: Pursuant to 40 CFR 790.55 and 790.68. EPA has approved by letter certain modifications to test standards and schedules for chemical testing programs under section 4 of the Toxic Substances Control Act (TSCA). These modifications, requested by test sponsors, will be incorporated and codified in the respective test regulation or consent order. Because these modifications do not significantly alter the scope of a test or significantly change the schedule for its completion. EPA approved these requests without seeking notice and comment. EPA will annually publish a notice describing all of the modifications granted by letter for the previous year. This is the third such annual notice.

EFFECTIVE DATE: This rule is effective on May 21, 1991.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, rm. E-543B. 401 M St., SW., Washington, DC

20460. (202) 554–1404. TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: EPA issued an interim final rule published in the Federal Register of September 1. 1989 (54 FR 36311), amending procedure for modifying test standards and schedules for test rules and testing consent orders under section 4 of TSCA The amended procedures allow EPA to approve requested modifications which do not alter the scope of a test or significantly change the schedule for it completion. These modifications are approved by letter without public comment. The rule also requires immediate placement of these letters in EPA's public files and publication of these modifications in the Federal Register. This document includes modifications approved from October 1. 1989, through December 31, 1990. For a detailed description of the rationale for these modifications, refer to the submitters' letters and EPA's responses in the public record for this rulemaking.

I. Discussion of Modifications

Each chemical discussed in this rule is identified by a specific CAS number and docket number. Copies of correspondence relating to specific chemical modifications may be found in docket number (OPTS-40020) or the chemical specific docket established for this rule. The following table lists all chemical-specific modifications approved from October 1, 1989, through December 31, 1990:

MODIFICATIONS TO TEST STANDARDS AND CONSENT ORDERS OCTOBER 1, 1989 THROUGH DECEMBER 31, 1990

Chemical/CAS Number	Chemical FR Cite	Test	Modifi- cations	Docket No.
Final Rule Chemicals:				
bis(2-chloroethoxy)methane (111-R1-1)	799.5055	N/A	8	40020/42088J
cumene (98-82-8)	700 1265	Acute toxicity test with:	1	40020/42074D
	733.1203	daphnia magna.		-0020/420/40
	.[Salmo queirdneri		11.
	ļ.	Cyprinodon variegatus		
	1	Mysidopsis batus		
diethylenetriamine (111-40-0)	799.1575	chemical fate		40020/42012J
Isopropanol (67-63-0)	795 260	developmental neurotoxicity test		40020/42097
	733.230	Coverage real ordering test	′	40020/4205/
unsubstituted phonylenediamine:				
m-pda (108-45-2), o-pda (95-54-5), p-pda (106-50-3)	799.3300	if triggered in one isomer: subchronic neurotoxicity, functional	5	40020/42008H
	1	observational battery (FOB), motor activity test (MAT), neuropathological studies.		· '
		If triggered in two isomers: subchronic neurotoxicity (FOB)		
		lest, motor activity test, neuropathology studies.	1	
	1	If triggered in three isomers; subchronic neurotoxicity (FOB)		
	1 .	test, motor activity test, neuropathology studies.		
	799.3300	scute toxicity testing in Gammarus		40020/42008H
	799.3300	Daphnie Life-cycle Test		40020/42008H
m-pga	. 799.3300	SLRL test, and acute toxicity in rainbow trout	5	40020/42008H
olyhalogenated dibenzo-p-dioxins/dibenzolurans:				
tetrabromobisphenol-A (79-94-7)		protocols submissions	5	40020/830020
2,4,6-tribromophenol (118-79-6)		protocols submissions	- 5	40020/830020
decabromodiphenyloxide (1163-19-5)		protocols submissions		40020/830020
1,2-bis(tribromophenoxy)-ethane (37853-59-1)		protocols submissions		40020/83002C
octabromodiphenyloxide (32538-52-0)	. ¹ 766.35	protocols submissions	5	40020/83002C

7

MODIFICATIONS TO TEST STANDARDS AND CONSENT ORDERS OCTOBER 1, 1989 THROUGH DECEMBER 31, 1990—Continued

Chemical/CAS Number	Chemical FR Cite	Test	Modifi- cations	Docket No.
allyl ether of tetrabromobisphenol-A (25327-89-3)pertabromodiphenyloxide (32534-81-9)tetrabromodisphenol-A-bisethoxylate (4126-45-2)	766.35 766.35	protocols submissions protocols submissions protocols submissions protocols submissions protocols submissions	5 5	40020/83002C 40020/83002C 40020/83002C 40020/83002C
mbutyl phoephate (126-73-8)	. 799.4369	pharmacokinetics, oral/dermal, developmental toxicity, vapor pressure, hydrolysis rate, sediment and soil adsorption isotherm, reproductive and fertility effects.	3,5	40020/42100C
triethylene glycol monomethyl ether (112-50-5)	799.4140	developmental neurotoxicity	5,7	40020/42080G
viny! fluoride (75-02-5)	799.1700	oncogenicity	· 6	40020/42002L
Consent Orders:				
alkyl phthalates	799.5000	fish early iiie stage studies analytical confirmation studies	3 3 5	40020/42092A 40020/42092A 40020/42092A
2 chloroaniline (95-51-2)	799.5000	rainbow trout early life-stage toxicity	5	40020/42054D
C.: Disperse Blue 79:1 (3618-72-2)	799.5000	rat development toxicity test		40020/42103A 40020/42103A
4-nom/lphenol branched (94852-15-3)	799.5000	octanoi/water partition coefficient, sediment and soil adsorp- tion isotherm.	5	40020/42104C
octamethylcyclotetrasiloxane (556-67-2)	799.5000	biodagradation studybioconcentration study		40020/42071D 40020/42071D
triethylene glycol monomethyl ether (112-50-5)	799.5000	dermal subchronic toxicity	3	40020/42080G

Modifications:

- Modify sampling schedule.
- Change to test substance (form/purity) 3. Change in non-critical test procedure or condition.
- Add satellite group for further testing.
- 5. Extend test or protocol deadline, delete test initiation date.
- 6. Clarify and/or add specific guideline
- 7. Alternate specific guideline requirement approved for certain test(s).
- CAS No. correction.

II. Public Record

EPA has established a public record for this rulemaking (docket number OPTS-40020). The record includes the information considered by EPA in evaluating the requested modifications.

The record is available for inspection from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays, in rm. G-004, NE Mall, 401 M St., SW., Washington, DC 20460.

III. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This rule, listing modifications of test standards and schedules for tests required under test rules and testing consent agreements under the authority of section 4 of TSCA, is not major because it does not meet any of the criteria set forth in section 1(b) of the Order.

This rule was submitted to the Office

of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq., Pub. L. 96-354, September 19, 1980), EPA is certifying that this rule will not have a significant impact on a substantial number of small businesses because the modifications listed in this rule have been made to expedite the development of test data and to reduce certain paperwork burdens associated with current regulations.

C. Paperwork Reduction Act

The information collection requirements associated with this rule have been approved by OMB under the provisions of the Paperwork Reduction Act. 44 U.S.C. 350l et. seq. and have been assigned OMB control number 2070-0033.

EPA has determined that this rule does not change existing recordkeeping or reporting requirements nor does it impose any additional recordkeeping or reporting requirements on the public.

Send comments regarding this rule to Chief. Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0033) Washington, DC

List of Subjects in 40 CFR Parts 766 and

Chemicals, Chemical export, Environmental protection, Hazardous substances. Reporting and recordkeeping requirements, Testing.

Dated: May 14, 1991.

Victor I. Kimm.

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR chapter I, subchapter E. parts 766 and 799 are amended as follows:

PART 766-[AMENDED]

- 1. In part 766:
- a. The authority citation for part 766 continues to read as follows:

Authority: 15 U.S.C. 2603 and 2607.

b. In § 766.35, by revising paragraphs (a)(2)(i)(B) and (b)(4)(i) and adding paragraph and (f) to read as follows:

766.35 Reporting requirements

- (2) (i) •
- (B) The protocol for each brominated chemical substance produced by each process to be tested must be submitted to EPA no later than 24 months after the effective date of this part except for the following chemicals.
- (1) The deadline for submitting the protocols for tetrabromobisphenol-A (CAS No. 79-94-7); 2,4,6 tribromophenol (CAS. No. 118-79-6);

decabromodiphenyloxide (CAS No. 1163–19–5); and 1,2-bis(tribromophenoxy)-ethane (CAS No. 37853–59–1) is January 31, 1991.

(2) The deadline for submitting protocols for octabromodiphenyloxide (CAS No. 32536-52-0) and allyl ether of tetrabromobisphenol-A (CAS No. 25327-89-3) is January 31, 1991.

(3) The deadline for submitting

(3) The deadline for submitting protocols for pentabromodiphenyloxide (CAS No. 32534–81–9) and tetrabromodisphenol-A-bisethoxylate (CAS No. 4126–45–2) is January 31, 1991.

(4) The deadline for submitting protocols for 3,4',5-tribromosalicylanilide (CAS No. 87-10-5) is September 5, 1990.

(b) • • •

(4) Test results. (i) Except as noted in the following specified substances, test results must be submitted to EPA not later than 270 days after EPA's transmission of comments or 180 days after a final protocol is submitted to EPA, whichever is shorter. The test results for 3,4'5-tribromosalicylanilide must be submitted 45 days after the test protocols have been approved by EPA. The test results for tetrabromobisphenol-A, 2,4,6 tribromophenol. decabromodiphenyloxide, 1,2bis(tribromophenoxy)-ethane, octabromodiphenyloxide, allyl ether of cetrabromobisphenol-A. pentabromodiphenyloxide and tetrabromodiphenol-A-bisethoxylate must be submitted no later than 45 days after EPA has notified the test sponsor that EPA has accepted the protocol or 135 days from the date of submission of the test protocol to EPA, whichever is later.

(f) Effective date. (1) The effective date of this final rule is July 6, 1987, except for paragraphs (a)(2)(i)(B) and (b)(4)(i) of this section.

(2) The effective date for paragraphs (a)(2)(i)(B) and (b)(4)(i) of this section is

May 21, 1991.

(3) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

PART 799-[AMENDED]

2. In part 799:

a. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. In § 799.1285 by redesignating paragraph (c)(3) "Neurotoxicity" as (c)(4), and by revising paragraphs ')(2)(ii)(A) and (g) to read as follows:

§ 799.1285 Cumene.

(d) * * * * (2) * * *

(ii) Reporting requirements. (A) The acute toxicity tests conducted with Daphnia magna, Salmo qairdneri, and Cyprinodon variegatus shall be completed and the final reports submitted to EPA by March 9, 1990. The acute toxicity test conducted with Mysidopsis bahia shall be completed and the final report submitted to EPA by May 13, 1990.

(2) Effective date. (1) The effective date of the final rule for cumene is September 9, 1988, except for paragraphs (d)(1)(i), (d)(1)(ii)(A), and (e)(1)(ii)(A) of this section. The effective date of paragraphs (d)(1)(i), (d)(1)(ii)(A), and (e)(1)(ii)(A) of this section is March 1, 1990. The effective date of paragraph (d)(2)(ii)(A) of this section is May 21, 1991.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

c. In § 799.1575, by revising paragraphs (d)(2) and (f) to read as follows:

§ 799.1575 Diethylenetriamine (DETA).

(d) · · ·

(2) Test standard. The testing shall be conducted in accordance with the following revised EPA-approved modified study plan (June 7, 1990) originally submitted by the Diethylenetriamine Producers/Importers Alliance (DPIA): "Modified Final Copy (04-17-90); Diethylenetriamine: Environmental Fate in Sewage, Lake Water and Soil". This revised EPA-modified study plan is available for inspection in the EPA's OTS Reading room, Room NE-G004, 401 M St., SW., Washington, DC 20460.

(f) Effective date. (1) The effective date of the final Phase II rule for diethylenetriamine is March 19, 1987, except for paragraphs (c)(4)(iii), (d)(2), and (d)(3) of this section. The effective date of paragraphs (c)(4)(iii), and (d)(3) of this section is March 1, 1990. The effective date for paragraph (d)(2) of this section is May 21, 1991.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule. d. In § 799.1700, by revising paragraphs (c)(4)(i) and (d) to read as follows:

§ 799.1700 Fluorcalkenes.

(c) · · ·

(4) Oncogenicity— (i) Required testing. (A) (1) Oncogenicity tests shall be conducted in both rats and mice by inhalation with VF in accordance with \$ 798.3300 of this chapter, except for the provisions in paragraph (b)(7)(vi) of \$ 798.3300.

(2) For the purposes of this section,

the following provisions also apply:

(i) Test procedures—observations of animals. All mice of test groups in which survival is approximately 25 percent of mice at risk (approximately 25 percent of 70, or approximately 18 mice) will be sacrificed near the time that 25 percent survival is achieved. All mice surviving the 18-month test period will be sacrificed and necropsied. The order of sacrifice for mice at all pathological evaluations will be random among all exposure groups within a sex Moribund animals should be removed and sacrificed when noticed.

(ii) [Reserved]

(B) Oncogenicity testing shall be conducted in mice with VDF in accordance with § 798.3300 of this chapter.

(C) Oncogenicity tests shall be conducted in both rats and mice with HFP if, after a public program review, EPA issues a Federal Register notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated.

(D) Oncogenicity tests shall also be conducted by inhalation in both rats and mice with TFE in accordance with § 798.3300 of this chapter if TFE yields a positive test result in any one of the following mutagenicity tests: The in vitro cytogenetics assay conducted pursuant to paragraph (c)(2)(i)(A) of this section, the mouse micronucleus cytogenetics assay conducted pursuant to paragraph (c)(2)(i)(B) of this section, the mammalian cells in culture assay conducted pursuant to paragraph (c)(1)(i)(A) of this section or the sexlinked recessive lethal assay in Drosophila melanogaster conducted pursuant to paragraph (c)(1)(i)(B) of this section if, after a public program review, EPA issues a Federal Register notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated. Criteria for positive test results are established in 40 CFR 798.5375, 798.5385, 798.5300 and 798.5275 of this chapter, respectively.

15

(d) Effective date. (1) The effective date of the final rule is July 22, 1987, except for paragraphs (c)(1)(i)(C)(1). (c)(1)(ii)(A), and (c)(4)(i), of this section. The effective date of paragraphs (c)(1)(i)(C)(1), and (c)(1)(ii)(A) is May 21. 1990. The effective date of paragraph (c)(4)(i) of this section is May 21, 1991.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the

final rule.

e. In § 799.2325 by revising paragraphs (c)(6)(i)(D) and (d) to read as follows:

§ 799.2325 Isopropenol.

(c) *

(6)

(D) The developmental neurotoxicity test shall be conducted with isopropanol in accordance with § 795.250 of this chapter, except for paragraph (c)(1)(iv).

(1) For purposes of this section, the

following provisions also apply:
(i) Numbers of animals. The objective is for a sufficient number of pregnant rats to be exposed to ensure that an adequate number of offspring are produced for neurotoxicity evaluation. At least 24 litters shall be used at each dose level.

(ii) [Reserved] (2) [Reserved]

(d) Effective dates. (1) The effective date of this rule is December 4, 1989, except for the provisions of paragraphs (c)(5)(i)(C)(1), (c)(5)(ii)(A)(3), (c)(6)(i)(D) of this section. The effective date for paragraphs (c)(5)(i)(C)(1) and (c)(5)(ii)(A)(3) is May 21, 1990. The effective date for paragraph (c)(6)(i)(D) is May 21, 1991.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the

final rule.

f. In § 799.3300 by revising paragraphs (c)(1)(ii)(A), (c)(3)(ii)(A), (e)(1)(ii), (e)(2)(ii) and (f) to read as follows:

§ 799.3300 Unsubstituted phenylenediamine. . . .

(1) • • •

(ii) Reporting requirements. (A) The tests shall be completed and the final reports for the MBMC assay shall be submitted to the EPA no later than January 16, 1991. The final report for the SLRL in Drosophila melanogaster shall be submitted no later than April 15,1991. (3)

(ii) Reporting requirements. (A) The acute neurotoxicity tests shall be completed and the final report submitted to EPA no later than September 15, 1990. If triggered, the final report of the subchronic neurotoxicity testing and the neuropathological examination shall be submitted to EPA on the following schedules. If one isomer is triggered, the reporting deadline is July 15, 1990. If two isomers are triggered, the reporting deadline is January 15, 1992. If three isomers are triggered, the reporting deadline is July 15, 1992.

(e) * * * * (1)

(ii) Reporting requirements. The final reports for acute toxicity testing shall be submitted as follows:

(A) Testing on the rainbow trout shall be completed and submitted to EPA 9 months after the effective date of the final rule for o-pda and p-pda. Testing for m-pda shall be completed and submitted by January 15, 1991.

(B) The acute toxicity testing in freshwater Gammarus shall be completed and submitted no later than

January 15, 1991.

(ii) Reporting requirements. (A) The fish partial life-cycle flow-through test shall be completed and final results shall be submitted to EPA no later than January 16, 1992.

(B) The invertebrate life-cycle flowthrough toxicity test shall be completed and the final report submitted to EPA no

later than July 15, 1991.

(C) Progress reports shall be submitted at 6 month intervals after the effective date of the final rule.

(f) Effective dates. (1) The effective date of this final rule is January 16, 1990, except for (c)(1)(i)(B), (c)(1)(ii)(A), (c)(1)(ii)(C), (c)(1)(ii)(F), (c)(3)(ii)(A), (e)(1)(ii) and (e)(2)(ii). The effective date of paragraphs (c)(1)(i)(B). (c)(1)(ii)(C) and (c)(1)(ii)(F) is May 21, 1990. The effective date of paragraphs (c)(1)(ii)(A), (c)(3)(ii)(A), (e)(1)(ii) and (e)(2)(ii) is May 21, 1991.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

g. In § 799.4360, by revising paragraphs (c)(2)(ii)(A), (c)(3)(ii)(A), (c)(8)(i). (c)(8)(ii)(A). (e)(1)(ii). (e)(2)(ii)(A), and (c)(3)(ii) and (f) to read as follows:

§ 799.4360 Tributyl phosphate.

(c) * *

(2) • •

(ii) Reporting requirements. (A) The developmental toxicity study required under paragraph (c)(2) of this section shall be completed and a final report submitted to EPA by January 27, 1991.

(ii) Reporting requirements. (A) The reproduction and fertility effects study required under paragraph (c)(3) of this section shall be completed and a final report submitted to EPA by August 17, 1992.

(8) * * *

(i) Required testing. (A) A pharmacokinetics test shall be conducted with TBP in accordance with § 795.228 of this chapter, except for the provisions of paragraphs (c)(1)(iii)(B), (c)(2)(ii)(C)(1) and (c)(2)(ii)(C)(2) of § 795.228.

(B) For the purposes of this section. the following provisions also apply:

(1) Animal care. During the acclimatization period, the animals shall be housed in suitable cages. All animals shall be provided with certified feed and

tap water ad libitum.

(2) Dermal treatment. For dermal treatment, two doses, comparable to the low and high oral doses, shall be dissolved in a suitable vehicle and applied in volumes adequate to deliver comparable doses. The backs of the animals should be lightly clipped with an electric clipper 24 hours before treatment. The test substance shall be applied to the intact clipped skin (approximately 2 cm² for rats, 40 cm² for mini-pigs). The dosed areas shall be protected with a suitable porous covering which is secured in place, and the animals shall be housed separately.

(ii) Reporting requirements. (A) The pharmacokinetics test required in paragraph (c)(8)(i) of this section shall be completed and the final report submitted to EPA by September 27, 1991

(1)

(ii) Reporting requirements. The vapor pressure test required in paragraph (d)(1) of this section shall be completed and the final report submitted to EPA by September 27, 1990.

(2)

(ii) Reporting requirements. (A) The sediment and soil absorption isotherm test required under paragraph (d)(2) of this section shall be completed and the final report submitted to EPA by September 27, 1990.

(3) • • •

(ii) Reporting requirements. The hydrolysis test required under paragraph (e)(3)(i) of this section shall be completed and the final report submitted to EPA by September 27, 1990.

(f) Effective date. (1) The effective date of this final rule is September 27, 1989, except for paragraphs (c)(2)(ii)(A), (c)(3)(ii)(A), (c)(8)(i), and (c)(8)(ii)(A), (e)(1)(ii), (e)(2)(ii)(A), and (e)(3)(ii) of this section. The effective date for paragraphs (c)(2)(ii)(A), (c)(3)(ii)(A), (c)(8)(i), and (c)(8)(ii)(A), (e)(1)(ii), (e)(2)(ii)(A), and (e)(3)(ii) is May 21, 1991.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

h. In § 799.4440, by revising paragraphs (c)(2), (c)(3)(i) and (d) to read as follows:

§ 799.4440 Triethylene glycol monomethyl ether.

(4) * * *

(2) For the purpose of this section, the following provisions also apply:

(i) Number of animals. The objective is for a sufficient number of pregnent rats to be exposed to ensure that an adequate number of offspring are produced for neurotoxicity evaluation. At least 24 litters are recommended at each dose level.

(ii) Dose levels and dose selection. In the absence of developmental toxicity or maternal toxicity the maximum dose shall be 5 grams/kilogram.

(i) The developmental neurotoxicity test shall be completed and the final report submitted to EPA within 21 months of the initiation of the test.

(d) Effective date. (1) The effective date of this final rule is May-17, 1989, except for paragraph (c)(2)(i) and (c)(3)(i) of this section. The effective date for paragraph (c)(2)(ii) and (c)(3)(i) of this section is May 21, 1991.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

i. In \$ 799.5055 by revising paragraphs
 (e)(1)(i)(A) and (f) to read as follows:

§ 799.5055 Hazardous waste constituents subject to testing.

(e) • • • • • (1) • • •

(i) Required test. (A) An oral gavage subchronic toxicity test shall be conducted in the rat with the substances designated in paragraph (c) of this section except for bis(2-chloroethoxy) methane (CAS No. 111-91-1) in accordance with § 798.2650 of this chapter.

(f) Effective date. (1) The effective date of the final rule is July 29. 1988, except for paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(ii). (e)(1)(i), and (e)(1)(ii)(A) of this section. The effective date of paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(ii), (e)(1)(i)(B) and (e)(1)(ii)(A) of this section is March 1, 1990. The effective date of paragraph (e)(1)(i)(A), is May 21, 1991.

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(2) The guidelines and other test methods cited here are referenced as they exist on the effective date of the final rule.

[FR Doc. 91-12012 Filed 5-20-91; 8:45 am]

17